

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1458V

Filed: October 31, 2018

UNPUBLISHED

DENISE GORING,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU); Fact Hearing; Findings of Fact; Onset; Site of Administration; Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Additional Non-covered Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); No Other Condition or Abnormality

Isaiah Richard Kalinowski, Maglio Christopher & Toale, PA, Washington, DC, for petitioner.

Voris Edward Johnson, U.S. Department of Justice, Washington, DC, for respondent.

FACT RULING¹

Dorsey, Chief Special Master:

On November 4, 2016, Denise Goring (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she suffered left shoulder injuries caused by vaccinations she received on October 19, 2015. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, the undersigned finds that petitioner’s Tetanus Diphtheria acellular Pertussis (“Tdap”) and shingles vaccines were administered in her left arm; that the onset of petitioner’s left shoulder injuries occurred within 48 hours of her October 19, 2015 vaccinations; and that a lipoma on petitioner’s

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

back was incidental and was not a condition or abnormality that explained her symptoms.

I. Procedural History Prior to Hearing

On November 4, 2016, Ms. Goring filed her petition (ECF No. 1). On the same day, she filed medical records marked as Exhibits 1-6 (ECF No. 4). She filed additional medical records, Exhibit 7, and a Statement of Completion on November 28, 2016 (ECF Nos. 9 and 10). The initial status conference was held on January 10, 2017 and respondent was directed to file a status report concerning the completeness of the records and how respondent intended to proceed in this case (ECF No. 11).

On February 3, 2017, petitioner filed an additional medical record marked as Exhibit 8 and an affidavit designated Exhibit 9 (ECF No. 12). On February 24, 2017, respondent filed a status report identifying missing records needed to determine respondent's position in this case (ECF No. 13). On the same day, petitioner filed a status report in response concerning the medical records identified by respondent and stating that petitioner sent a demand letter to respondent on February 24, 2017 (ECF No. 14).

On February 27, 2017, the undersigned issued a scheduling order directing respondent to file a status report proposing appropriate next steps (ECF No. 15). From March to June 2017 the parties engaged in discussions attempting to informally resolve this matter (ECF Nos. 16-23). On July 20, 2017, petitioner filed a status report informing the court that the parties had been unable to resolve the matter informally and proposing that the court schedule a deadline for the filing of respondent's Rule 4(c) Report (ECF No. 25). On July 21, 2017, petitioner filed additional medical records as Exhibit 10 (ECF No. 28).

On August 10, 2017, respondent filed a Rule 4(c) Report (ECF No. 29). The court scheduled a status conference to discuss with the parties how to proceed. Before the status conference took place, on August 28, 2017, petitioner filed a motion for summary judgment (ECF No. 30). The August 28, 2017 status conference was cancelled, respondent filed a response to the summary judgment motion (ECF No. 31), and petitioner filed a reply (ECF No. 32). Petitioner filed an additional affidavit on September 20, 2017 (ECF No. 33).

On October 4, 2017, the undersigned denied the summary judgment motion (ECF No. 34) and directed petitioner to file additional affidavits, medical records, and an expert report (ECF No. 35). On December 13, 2017, petitioner filed additional medical records, a detailed affidavit, and medical literature (ECF Nos. 39 and 40). Also on December 13, 2017, petitioner filed a status report and request for a status conference (ECF No. 41).

On January 23, 2018, the undersigned held a status conference with counsel for both parties. On January 24, 2018, petitioner filed a status report confirming that she sent a detailed counter-offer to respondent (ECF No. 44). On February 1, 2018, the undersigned issued an order directing petitioner to obtain an expert report addressing a lipoma on petitioner's back as an alternative cause of her shoulder condition. Scheduling Order, issued Feb. 1, 2018 (ECF No. 45). In the February 1, 2018 order,

the undersigned further stated that absent additional evidence, the undersigned was inclined to rule that respondent had not met his burden of proving alternate causation, in this case whether a vaccine not covered by the Vaccine Act had caused petitioner's injury.

On April 24, 2018, petitioner filed medical records from Dr. Ellis Nam of Chicago Orthopaedics & Sports Medicine, S.C. (ECF No. 50-2). On May 30, 2018, petitioner filed a May 18, 2018 addendum to Dr. Nam's earlier records (ECF No. 53-2). On May 30, 2018, the parties and OSM staff attorneys held a status conference to discuss how to proceed. On June 1, 2018, the undersigned issued an order determining that the case should proceed to a hearing to resolve the onset of petitioner's symptoms, the site of administration of petitioner's vaccinations, and whether a lipoma on petitioner's back was a condition or abnormality that would explain her symptoms (ECF No. 54). A fact hearing was thereafter scheduled for September 18, 2018.

II. Fact Hearing and Ruling

A fact hearing was held in Washington, D.C., on September 18, 2018. Ms. Goring was the sole witness and she appeared in person with her attorney. At the conclusion of the hearing, the undersigned informed the parties that she intended to issue a ruling from the bench. The undersigned stated that her ruling would resolve the site of vaccine administration, whether the onset of petitioner's symptoms occurred within 48 hours of vaccination, and the role of a lipoma on petitioner's back.

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and Aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a Table SIRVA claim, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id.; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

With these factors in mind, the undersigned made the following preliminary findings of fact:

There are several issues that require this fact hearing today. They include -- the several fact issues, they include the site of administration, onset, and the role of the lipoma.

First, as to the site of the tetanus and shingles vaccine injections, I find that they were administered into Petitioner's left arm. I base this on a number of medical record -- a number of pieces of medical record evidence. First, the Petitioner's Exhibit 1, the vaccine administration record shows that the Petitioner received three vaccines on October the 19th, 2015, including the Tdap vaccine. Secondly, Petitioner's Exhibit 3 at 42, Dr. Noriega charted at that visit, December 22nd of 2015, that the Petitioner had left arm pain after two shots. Similarly, Dr. Townsend documented that the Petitioner complained of left shoulder pain that began after receiving two immunizations in the left arm. That was documented January 26th, 2016. Exhibit 3 at page 326.

Similarly, the Center for Progressive Health, that's the natural physician, documented on February the 2nd, 2016, left shoulder pain following tetanus and shingles shots in left deltoid in October. Exhibit 2 at pages 3 and 4. Additionally, that is consistent with the Petitioner's testimony here today. Also, the medical records by the physical therapist, Shawn White, Exhibit 5 at pages 54 and 56. All of these records are consistent, showing the Petitioner consistently reported to healthcare providers, different healthcare providers, who all documented that she received her tetanus and shingles vaccines and that they were administered in her left arm. For these reasons, I find the site of her tetanus and shingles vaccines to be her left deltoid.

With regard to onset, I find that the onset of pain, the initial manifestation of pain in Petitioner began within 48 hours. I base this on a number of pieces of evidence. I think the strongest evidence is that written by Dr. Perrott on February 18th, 2016, when he documented "injections in left deltoid since October" and "since then" had pain in left shoulder region. Exhibit 14 at page 3. This is also documented by Dr. Noriega on December 22nd, 2015, at Exhibit 3 at page 42; however, he used the words "left arm pain after two shots." Similarly, Dr. Townsend Scott documented left shoulder pain that began after receiving two immunizations in the left arm. Exhibit 3 at 326. And, again, the Center for Progressive Health, "left shoulder pain following tetanus and shingles shots in left deltoid" in October. Exhibit 2 at pages 3 and 4. Additionally, I find that Petitioner's testimony here today to be consistent with a very detailed explanation as to the pain and then the weakness and reduced range of motion that she experienced. I find that her pain began within 48 hours of receiving the tetanus and shingles shots in her left arm.

The next issue is the role of the lipoma. Ms. Goring was seen in the Mercy Hospital Emergency Room on January 19th, 2016, by Dr. Krishna [Raol] and Dr. Michael Joo On intake, Petitioner reported that she had been having left shoulder pain after she received two immunizations in that arm about two months ago. A CT of the chest was done which showed a large [fat] density mass deep to the left serratus anterior and latissimus dorsi muscles. The impression was "Fat density mass overlying the posteriolateral left chest wall to the same muscles, which likely represents a lipoma." The diagnosis was "Shoulder pain likely related to rotator cuff pathology, possibly related to large lipoma." And Ms. Goring was instructed to follow up with her PCP. Exhibit 3 at page 298. Ms. Goring did follow up and had additional evaluation. She saw Dr. Perrott on February 18th, 2016. Dr. Perrott diagnosed her with an incidental lipoma and noted that the Petitioner agrees that excision of this is unlikely to change her shoulder problem. He charted "Shoulder, questionable rotator cuff syndrome as cause of discomfort," and referred her to PT. Exhibit 14 at 3.

Following that, she saw Dr. Nam in March, March 8th, 2018. Dr. Nam documented, "She is inquiring if a lipoma on her back resulted in her left shoulder condition. I believe her lipoma seen in her CT scan of her left upper back was unrelated to her left shoulder condition she developed after her vaccination." Exhibit 24 at page 3. Dr. Nam also documented an addendum on May 18th, 2018, in which he states:

Patient has an incidental lipoma on her back which was unrelated to her left shoulder condition she developed as a result of the tetanus/shingles shot in her left shoulder on October 2015. The lipoma's location is not on her back and not on her left shoulder. They are in separate, distinct anatomical locations in her body. As a result, the lipoma has no relationship to her left shoulder and has no influence in Denise developing left shoulder pain after her injection she received in October 2015.

Exhibit 24 at page 2.

Thus, I find that Dr. Nam has clarified the condition of lipoma, which was raised as a possible issue by the emergency room physicians, and I find that his opinions are reasonable, valid, and credible, as well as persuasive, and, thus, I find, as Dr. Nam did, I find that his opinion that the lipoma is incidental and not related or causally related to her shoulder injury related to vaccine administration or shoulder injury, I find that it is not related.

These are my opinions or my factual findings, and that is the end of my factual findings.

Transcript of September 18, 2018 Hearing, ECF No. 63, at 82-86.³

III. Closing of the Record Regarding Entitlement

Following the hearing, the undersigned took judicial notice of two articles pertaining to causation of vaccine-related shoulder injuries which were filed as court exhibits. These articles are: B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I, and M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Court Exhibit II (ECF No. 64).

The parties have been provided until December 7, 2018 to provide additional evidence concerning entitlement or any response to the court exhibits, and memoranda addressing the implications of petitioner's receipt of a vaccine covered by the Vaccine Program and a non-covered vaccine in her injured arm. *Id.* Thereafter, the record will close and the undersigned will issue a decision or ruling on entitlement.

IV. Conclusion

In light of all of the above, and in view of the submitted evidence, including the medical records, credible witness testimony, and findings of fact, **the undersigned finds that the site of administration of petitioner's Tdap and shingles vaccinations was her left arm; that the onset of petitioner's right shoulder injuries was within 48 hours of vaccination; and that petitioner's back lipoma was incidental and not a condition or abnormality that would explain her symptoms.**

A scheduling order has been issued granting the parties until December 7, 2018 to submit any additional evidence on entitlement and allowing the parties to file memoranda of law addressing the implications of the fact that petitioner received both a vaccine covered by the Vaccine Program and a non-covered vaccine in her injured arm. (ECF No. 64). **After the record closes, the undersigned intends to issue a decision or ruling on entitlement based on all the evidence submitted into the record, and consistent with the findings set forth in this ruling.**

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master

³ This ruling is not a verbatim transcript of the undersigned's bench ruling. It includes minor changes for the purpose of readability.